FOR ARGUMENT

No. 89-243

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY BRIEF ON THE MERITS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Legislative Materials:

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SUMMARY OF THE ARGUMENT

It defies basic tenets of statutory construction and common sense to suggest, as respondent Medtronic, Inc. ("Medtronic") does with its contortions of logic, that the restrictive statutory language "development and submission of information under a Federal law which regulates . . . drugs" means the development and submission of information for any product under the more expansive Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Congress would not, and did not, use a narrow term–"drugs," which expressly excludes devices under the FD&C Act–to include devices and all other products covered by the much broader FD&C Act.

The "plain language" argument of Medtronic and some of its supporting *amici* contradicts the Court of Appeals' opinion below. Medtronic does not attempt to support the

reasoning of the Court of Appeals' opinion. The Court of Appeals, Medtronic, and its supporting *amici* also disagree over Medtronic's argument that there is clear support in the legislative history for inclusion of "medical devices" in Section 271(e)(1). The positional chaos among Medtronic and its supporting *amici* results from the inescapable language of the statute in question limiting its application solely to drugs.

Neither Medtronic nor its supporting *amici* can point to a single reference in the legislative history of Section 271(e)(1) suggesting the possibility of exempting medical devices from patent infringement. There are none. Instead, Medtronic reconstructs the legislative commentary of Sections 271(e)(1) and 156 to distort Section 271(e)(1). The House Committee reports clearly distinguish between the scope of Section 271(e)(1) (drugs) and Section 156 (drugs, medical devices, food additives, and color additives) in both the language of the statute *and* the textual discussion. H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 15, 17, 20 (1984).

In apparent recognition of the infirmity of its statutory arguments, Medtronic improperly raises for the first time in this litigation a new issue–a judicially-created "experimental use" exception to patent infringement. Even if the argument were considered, however, this alleged common law infringement exemption has no merit. As Medtronic's supporting *amicus* Dr. Denton Cooley admitted, "the present law . . . does not exempt from infringement experimental use where there is an ultimate commercial motive, however remote." Cooley Br., pp. 3-4.

Under the guise of testing for regulatory approval, Medtronic and its supporting *amici* desire the right to copy and infringe any patent for medical devices, food additives, color additives, and all other FDA-regulated, non-drug

products throughout the entire patent term.[1] Medtronic's policy arguments (strongly countered by Lilly and its supporting *amici*) are appropriate for Congress, not this Court, to consider. "Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *United States v. Rutherford,* 442 U.S. 544, 555 (1979).

ARGUMENT

I. The Plain Language of the Statute Expressly Limits Section 271(e)(1) to Development and Submission of Regulatory Information Necessary for Drug Approval

Instead of reading Section 271(e)(1) as a whole and giving meaning to all of its words, Medtronic improperly combines isolated interpretations of selected phrases to artificially support its position. Medtronic first interprets the phrase "patented invention," and, overlooking the language "solely for uses reasonably related to the development and submission of information under," construes the phrase "Federal law which regulates . . . drugs" to mean the *entire* FD&C Act. Medtronic then makes a tortuous leap in logic to conclude that since Medtronic's medical devices may be described as a "patented invention" and since its testing is done under the FD&C Act, the criteria of Section 271(e)(1) are met. Medtronic Br. p. 6. Medtronic's piecemeal interpretation of Section 271(e)(1) is compelling

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[1] It is ironic that Medtronic, which once owned the patent rights in suit in the early 1970's but abandoned an implantable defibrillator project for, *inter alia,* marketing reasons (Pet. App. 24a; Tr. Ex. 173; Trans. Day 2; 30-32), claims to be the protector of the public interest. Medtronic and some of its supporting *amici* stood on the sidelines for a decade or more letting Dr. Mirowski, Lilly, and Lilly's predecessors-in-interest assume the entire financial risk to obtain therapy acceptance for the pioneer lifesaving implantable defibrillator. Once therapy acceptance was achieved, these competitors then decided to launch their infringing imitative implantable defibrillators.

evidence of its strained, improper statutory construction.[2]

The restrictive language "development and submission of information under a Federal law which . . . regulates drugs" means what it says. It grants a narrow exemption from patent infringement for development and submission of regulatory information necessary for *drug* approval.[3] Although referring to the drug provisions of more than one Act of Congress, the statute does not encompass the entire FD&C Act. It is restricted to regulatory submissions under a "Federal law regulating . . . drugs," not any submissions under the FD&C Act, a term used only a few lines earlier in the same subsection. Medtronic's statement that the phrase "under a Federal law regulating . . . drugs" refers to provisions in more than one Act of Congress is meaningless. The language still is limited to the *drug* submission provisions of those acts.

Medtronic's infringing devices never can be used "for development and submission of information *under* a Federal law which regulates . . . drugs." (emphasis added). Information for premarket approval requirements of (human) drugs is developed and submitted under drug provisions such as 21 U.S.C. § 355 (human pharmaceuticals).[4] In contrast, Medtronic's infringing devices are used

[2] Under Medtronic's interpretation, the same outcome — bringing medical device testing within Section 271(e)(1) — would result had the last phrase of the statute read "Federal law regulating . . . color additives," or for that matter, "foods" or "cosmetics." The plain language does not support an interpretation that any product is covered by Section 271(e)(1) merely because it happens to be regulated in an Act of Congress that *also* regulates drugs.

[3] Medtronic is wrong in its argument that Lilly narrows the definition of the term "patented invention" to mean "drug-related invention." Medtronic Br. p. 10. Lilly interprets Section 271(e)(1) only as required by its operative language and correct tenets of statutory construction. Medtronic's reliance on the rules of grammar and syntax is misplaced.

[4] Contrary to Medtronic's allegations, Lilly does not maintain that a "Federal law which regulates . . . drugs" refers *only* to 21 U.S.C. § 355. However, if animal drugs and veterinary biological products are excluded, as in the original enactment of Section 271(e)(1), Section 355 constitutes the predominant law *under* which information for premarket approval of drugs is developed and submitted.

for development and submission under a Federal law which regulates devices, *i.e.*, 21 U.S.C. §§ 360e and 360j. Data submission requirements for food additive petitions and color additive petitions are described in 21 U.S.C. §§ 348 and 376, respectively. It would be odd, to say the least, for Congress to identify the data submission and approval requirements for medical devices, food additives, and color additives as being under a "Federal law which regulates . . . drugs."

It is true that drugs, devices, and other products may be regulated under the same Act, such as the FD&C Act.[5] However, as Medtronic admits (Medtronic Br. p. 20), devices are not regulated, nor is information developed or submitted for governmental approval, *under* any drug provision or under the designation "drugs." Drugs and medical devices are distinct and separate products.[6] The FD&C Act

[5] Medtronic relies upon 21 U.S.C. § 331 as regulating both drugs and devices. This argument is irrelevant, and merely advances a more narrow version of its erroneous conclusions drawn from the FD&C Act being a law that regulates drugs and devices as well as other products. No information is developed or submitted under 21 U.S.C. § 331. Moreover, *Section 331 treats drugs and devices distinctly.* Although it may prohibit certain acts relating to drugs, devices, foods, and cosmetics, Section 331 offers no support that medical devices are a subset of drugs or are included in the meaning of the term "drugs," or that Congress mistakenly thought so. The language of 21 U.S.C. § 331 actually negates Medtronic's arguments. It is further proof that whenever Congress enacts statutes covering medical devices and drugs, it speaks clearly and identifies *each* by name. In contrast, Section 271(e)(1) only identifies drugs.

[6] Medtronic alleges that "a bright line between [drugs and devices] does not exist." Medtronic Br. p. 41. This is another of Medtronic's irrelevant arguments highlighting the desperation of its Section 271 (e)(1) interpretation. In rare cases, there may be a dispute about whether a product is a drug, medical device, or both. Many ramifications result from the selected classification, including, *inter alia*, the governing provisions of the FD&C Act. Before any testing begins, however, the FDA determines the classification of the product with an opportunity for court review from dissatisfied requesters. Once the classification is made, there is no dispute about which regulations govern the development and submission of information to obtain FDA approval for drugs or medical devices. In fact, 35 U.S.C. § 156 requires that a distinction between drugs and devices be made, and treats patent extensions for the two differently. In any event, to the extent there is a "bright line" distinction between these two types of products, it is completely irrelevant to the statutory interpretation in question.

expressly states that the "term 'drug' . . . does not include devices or their components, parts, or accessories." 21 U.S.C. § 321(g)(1). There hardly could be a more inappropriate phrase to identify medical device uses than "uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs."

II. Medtronic Misuses Related Statutory Language and the Legislative History

A. Sections 271(e)(2) and (e)(4) Are Equally Necessary for Devices Had Section 271(e)(1) Included Medical Devices

In its main brief, Lilly explains that had Congress included medical devices in Section 271(e)(1), it also would have included medical devices in the patent holder protection provisions of Sections 271(e)(2) and (e)(4). Petitioner's Br. pp. 17-18. *Compare* proposed Senate Bill S.622 which would add medical devices to Sections 271(e)(1), (e)(2), and (e)(4) (Pet App. 60a-61a). Medtronic attempts to address this glaring omission from their version of the statute by theorizing that those special protections are unnecessary for medical devices. Medtronic then states "there are no provisions, comparable to those for drugs, for abbreviated safety and efficacy testing of medical devices *in the class of implantable defibrillators.*" Medtronic Br. p. 29 (emphasis added). Medtronic's statement misses the point.[7]

[7] While "abbreviated" applications (*i.e.*, those involving bioequivalence testing) are unavailable for medical devices, many medical devices other than implantable defibrillators do not require full premarket clinical trials prior to marketing. As Medtronic's supporting *amicus*, the American Association of Retired Persons ("AARP"), explained, the vast majority of medical devices can qualify for marketing without clinical trials if they are "substantially equivalent" to a device marketed before 1976. AARP Br. p. 12. *See*, 21 U.S.C. §§ 360c(a)(3), c(c)(2), and c(f)(1); 21 C.F.R. § 814.1(c)(1). Medtronic's selection of implantable defibrillators (which are not eligible for marketing under the "substantially equivalent" provisions) as "exemplary" is misleading and highlights the error of its argument.

Section 271(e)(2) provides an early mechanism for the patent holder to initiate an infringement action where an infringer seeks abbreviated regulatory approval (35 U.S.C. § 355j) and commercialization before the patent expires. Without the special protections of Sections 271(e)(2) and (e)(4), the patent holder would have to wait until the infringer operates outside the scope of Section 271(e)(1), and would suffer monetary damage as well as irreparable injuries during the inherent delays of the litigation process. As evidenced by proposed S.622, the special patent protections of Sections 271(e)(2) and (e)(4) would have been equally necessary and available for medical devices had Congress included medical devices in Section 271(e)(1).

B. The Separate Products Covered by Sections 271(e)(1) and 156 Are Clearly Identified

In its main brief, Lilly explains that the statutory language of the patent extension provisions (Section 156) refers expressly to both drugs and devices while the statutory language of Section 271(e)(1) refers only to drugs. Petitioner Br. pp. 18-21. This disparate inclusion and exclusion in different portions of the same Act reveals that Congress purposely excluded medical devices from Section 271(e)(1). *See, e.g., Russello v. United States,* 464 U.S. 16, 23 (1983).

Medtronic argues that these differences in statutory language are irrelevant because the "entire legislative history suggests that [Section 156] is solely concerned with drugs" and thus "would compel the Court to draw the manifestly incorrect conclusion that Congress did not provide patent term extension for devices." Medtronic Br. p. 36.

Medtronic's premise is erroneous. In its section entitled "Purpose and Summary," House Report No. 98-857 clearly recognizes that Section 271(e)(1) covers only drugs while Section 156 covers drugs, devices, and other products.

> Title II of H.R. 3605 [Section 156] provides for one extension of the earliest patent on certain products subject to pre-market approval. . . . These products include: human drugs, animal drugs, *medical devices, and food and color additives.*
>
> * * *
>
> Finally, Title II [Section 271(e)(1)] provides that it is not an act of patent infringement for a *generic drug maker* to import or to test a *patented drug* in preparation for seeking FDA approval if marketing of the *drug* would occur after expiration of the patent.

H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 15 (1984) (emphasis added). The purpose and summary of the legislative history could not be more clear as to which products are encompassed by Sections 271(e)(1) and 156, respectively.[8]

C. Medtronic Distorts the Legislative History

Medtronic and its supporting *amici* could not point to a single reference in the legislative history suggesting that medical devices are included within Section 271(e)(1). In a transparent attempt to manufacture support, Medtronic surgically reconstructs that portion of the legislative history upon which it relies. Medtronic Br. p. 24. In doing

[8] Additional legislative commentary identifies the specific products within the separate scopes of Sections 271(e)(1) and 156. *See, e.g.*, H.R. Rep. No. 857, *supra*, Part 1, at 17 ("the products covered by [the patent extension provisions] include pharmaceuticals, medical devices"); *id.*, Part 1, at 20 ("products affected by [patent extension] would be drugs, medical devices . . ."); *id.*, Part 1, at 44 (paragraph entitled "Medical Devices" under Section 156); *id.*, Part 2, at 24 (Section 156(f) includes medical devices); *id.*, Part 2, at 32 ("products affected by [patent extension provisions] would be drugs, medical devices . . ."). *See also*, the Brief for the Petitioner, which sets forth the citations to the legislative history that limit Section 271(e)(1) solely to drugs. Petitioner's Br. pp. 22-24.

so, Medtronic excises key prefatory language immediately preceding the language quoted by it, and then selectively transplants language to relocate one sentence in the place of another (likewise omitted). Medtronic Br. p. 24. *Compare* H.R. Rep. No. 857, Part 1, at 45-46. The language excised by Medtronic from the legislative commentary is italicized below and the relocated sentence is noted:

> *The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.*
>
> *In Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., ____ F.2d ____ (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the experimental use of a drug product prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee's view that* experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date **[MEDTRONIC RELOCATED THIS SENTENCE IN PLACE OF THE OMITTED (ITALICIZED) SENTENCE IN THE NEXT PARAGRAPH].**

> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged. *For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product.* Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. Rep. No. 857, Part 1, at 45-46 (emphasis added).

The excised language shows that the limited experimental activity exempted by Section 271(e)(1) *is bioequivalence testing* for generic drugs.[9] Medtronic labels the Congressional statement that Section 271(e)(1) permits only bioequivalence drug testing "an understandable lapse." Medtronic Br. p. 31, n.26. Medtronic's inability to otherwise explain this legislative commentary further undermines its flawed interpretation.

There is no basis for applying the specific legislative commentary on Section 271(e)(1) to medical devices, food additives, or color additives, the other products for which the patent extensions of Section 156 apply. Analysis of the last paragraph of H.R. Rep. No. 857 reproduced above, especially the sentence omitted by Medtronic on two

[9] While the statute also would permit *clinical* testing of patented drugs, Congress understood, as a practical matter, that manufacturers would take advantage of the "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own time-consuming clinical tests. *See* H.R. Rep. No. 857, Part 2, at 8. Medtronic's argument that Section 271(e)(1) applies to clinical testing of patented drugs (other than generic bioequivalence testing) raises another empty point, with no real-world consequences.

occasions (Medtronic Br. pp. 24 and 35), reveals the action Congress took to encourage immediate competition for patented drugs. "*For that reason,* Title I of the bill permits the *filing of abbreviated new drug applications* before a patent expires and contemplates that the *effective approval date will be the expiration date of the valid patent covering the original product.*" *Id.*, Part 1, at 46 (emphasis added). The Congressional action on Section 271(e)(1) does not apply to medical devices.[10] Under Medtronic's interpretation, medical devices can be approved anytime during the patent term because there are no Section 271(e)(2) and (e)(4) restrictions, and no regulatory exclusivity provisions or automatic provisions to delay the effective approval date as there are with drugs under 21 U.S.C. § 355(j)(4)(B). In the absence of express language, it cannot be presumed, as Medtronic urges, that Congress would take away valuable intellectual property rights from medical device patent holders.

D. Sections 156 and 271(e)(1) Are Not Coextensive in Scope or Nature

As a secondary argument, Medtronic alleges that Sections 271(e)(1) and 156 are coextensive and thus should be construed to be equal in scope, *i.e.*, since Section 156 applies to devices as well as drugs, so should Section 271(e)(1). Medtronic Br. p. 23. Again, Medtronic's premise is without merit. Section 271(e)(1) is not congruent to or coextensive with Section 156. Section 271(e)(1) applies to all drug patents whether the patent term is extended or not, and even applies to those drug patents which cannot qualify for a term extension. In contrast, only a handful of patents in an FDA-regulated field can be extended under the restrictive eligibility provisions of Section 156(a). *Cf.*

[10] Medtronic's alleged justification for Section 271(e)(1) as being a *quid pro quo* for Section 156 does not apply to food additives and color additives. When a regulation is issued to govern the use of food or color additives, a copier can market its version promptly upon the expiration of the patent without any requirement to obtain FDA approval comparable to what is required for drugs. 21 U.S.C. §§ 348 (a)(2), 376(a).

Fisons PLC v. Quigg, 872 F.2d 99 (Fed. Cir. 1989) (patent term extension denied for three drug patents); *In re Alcon Laboratories Inc.*, 13 U.S.P.Q. 2d 1115 (Pat. Comm'r 1989) (patent term extension denied for drug patent).

Section 271(e)(1) applies anytime during the entire term of affected patents. On the other hand, the patent holder does not recover the full amount of patent life lost during testing and the FDA regulatory approval process.[11] 35 U.S.C. §§ 156(c) and (g). Sections 271(e)(1) and 156 were never intended to be coextensive in scope.

Contrary to Medtronic's arguments, the complementary exclusion of animal drugs and veterinary biological products from Sections 271(e)(1) and 156 does not establish congruency. Animal drugs and veterinary biological products are included in the definition of the term "drug" in the FD&C Act. *See* 21 U.S.C. § 321(g)(1); *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288, 1289 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982) (the term "drug" encompasses animal biologics). Thus, it was necessary to exclude expressly animal drugs and veterinary biological products in the original enactment of Section 271(e)(1) when Congress decided to address them in separate legislation.

III. Public Policy and Constitutional Considerations

A. Public Policy

The policy arguments raised by Medtronic and its supporting *amici* are for Congressional consideration. *Rutherford*, 442 U.S. at 555. Lilly and its supporting *amici* have set forth the policy considerations strongly favoring Congress' exclusion of medical devices and other non-drug,

[11] Although Lilly's predecessors-in-interest spent *over fourteen years* in testing and seeking FDA approval for its implantable defibrillators from 1971 (issuance of the '757 patent) until 1985 (FDA premarket approval granted), Lilly could only obtain a *two-year* patent extension for the '757 patent under Section 156. Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.

FDA-regulated products from Section 271(e)(1). Petitioner Br. pp. 28-33. They will not be repeated here. The Senate Committee report on the proposed patent extension provisions in 1981 further discusses the policies supporting patent term extension. Senate Rep. No. 97-138, 97th Cong., 1st Sess., at 8-9 (1981).[12]

After a patent expires, a patent holder generally has no right to exclude others under that patent from making, using, or selling the patented invention. Exclusion of medical devices from Section 271(e)(1) gives Lilly no additional patent rights. Cases cited by Medtronic involving expansion of patent rights are inapposite.

If there are any commercial ramifications of the DPC-PTR Act that favor Lilly, those are a function of the FDA approval process, not the Congressional legislation at issue. For example, a copier can avoid any inherent delay in the FDA approval process by obtaining FDA approval prior to patent expiration based solely upon foreign activities (assuming foreign patent rights are not infringed).[13] 21 C.F.R. § 814.15; JA 107-8. It is the copier, not Lilly or

[12] That Committee Report stated that the patent term extension provisions, which then were without any accompanying patent infringement exemption, "will have a particularly beneficial effect on small research-oriented companies." Senate Rep. No. 97-138, *supra*, at 8. The AARP in 1981, before the *Roche v. Bolar* decision, submitted a written statement in support of the concept of patent term restoration although Section 271(e) (1) exemptions were unavailable. *Id.*, at 8. This alone contradicts most of the AARP policy arguments made in this case. At the same time, representatives of the university research community (Johns Hopkins University and Massachusetts Institute of Technology) stated that the patent extension provisions benefit universities. *Id.* This contradicts the policy arguments of the *amici* self-proclaimed as the "Academic Research Centers" (consisting solely of the University of Minnesota and Tulane University).

[13] There is an inherent delay in achieving full commercial productivity for copiers of *all* patented products, not just FDA-regulated products, after the expiration of the patent. The patent laws do not allow testing or mass manufacturing and warehousing of infringing products during the patent term even if the infringer is gearing up only for commercialization after patent expiration. *See Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 16-20 (Fed. Cir. 1984) (testing solely for post-patent commercialization is an infringement).

the patent laws, that ultimately controls whether the copier can market its products immediately upon expiration of the patent.

The arguments of Medtronic and its supporting *amici* that "the sky is falling" on American research and development if Section 271(e)(1) excludes medical devices and other FDA-regulated products are unfounded. The FDA regulations governing medical devices have been in effect since 1976. Until Medtronic raised the defense of Section 271(e)(1) in 1987 (three years after its enactment and four years after this litigation commenced), Lilly was not aware of anyone expressing a concern that American research would relocate to foreign countries if an FDA-testing patent exemption were not available for devices. The track record since 1976, when FDA testing regulations for devices began and patent laws prohibited all use of infringing products, including FDA testing, prior to patent expiration, shows there has been no mass exodus of American research talent or resources.

Moreover, Medtronic's reasoning also would apply to U.S. research related to *all* U.S. patents during the term of the patent since the patent laws prohibit pre-expiration testing of an infringing product intended solely for post-patent use. *Paper Converting,* 745 F.2d at 16-20. Despite these restrictions, the patent laws exist "in the hope that '[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens'." *Diamond v. Chakrabarty,* 447 U.S. 303, 307 (1980). Medtronic has turned this policy favoring a strong patent system on its head and applied it to infringers. Favoring improvements by infringers at the expense of eroding the stimulus for basic lifesaving inventions conflicts with the purposes of the patent system.

The only research restricted is the making, using, and selling of patented inventions, nothing more. But for the patented inventions, there would be nothing to copy, and no basic invention to improve.

The several conflicting *amici* briefs filed by interested parties from the medical device industry show that the policy arguments are for Congressional consideration in the first instance, not judicial resolution. This Court must reject Medtronic's blatant request for judicial legislation seeking a judicial response to Congress' actions and inactions. *See* Medtronic Br. p. 38, n.32.

B. Constitutional Considerations

Despite charging more than $17,000 per device (JA 108) and proclaiming itself "the technological leaders in the tachy arena" after its first clinical PCD implant (JA 128-29), Medtronic, without support, opines that the unconstitutional "taking" of property from device patentees is identical to that considered by Congress in the limited context of bioequivalence testing for generic drugs. Medtronic Br. p. 39 n.33. Medtronic simply fails to appreciate that resolution of the Constitutional issues (*i.e.,* impermissible taking under the Fifth Amendment) can be avoided, and must be avoided, only by limiting Section 271(e)(1) to testing for drugs. *See* Petitioner's Br. pp. 31-32.

IV. Medtronic Improperly Raises a New Argument for the First Time In This Appeal

Medtronic now attempts to assert a new issue–an alleged judicially-created experimental use exception to patent infringement. Medtronic Br. pp. 44-48. This "defense" has been waived. It was never pleaded in the Answer to the Complaint, raised in the lower courts, or argued in Medtronic's opposition to Lilly's certiorari petition. The grant of certiorari is premised exclusively upon statutory construction of Section 271(e)(1). This Court must not consider Medtronic's new argument presented for the

first time in its brief in response. *See, e.g., Youngberg v. Romeo,* 457 U.S. 307, 316 n.19 (1982) (this Court declined to consider an argument raised for the first time in respondent's brief); *FTC v. Grolier, Inc.,* 462 U.S. 19, 23 n.6 (1983).

Lilly objects to Medtronic's presentation of this new issue which is clearly outside the statutory interpretation question presented to this Court in the petition for certiorari. However, without waiver of its objection, Lilly will address the issue briefly.

Medtronic seeks an across-the-board exemption to patent infringement for all FDA testing of medical devices, and presumably for all other FDA-regulated products. Medtronic Br. p. 44. This would be a gross act of judicial legislation and infringe upon the exclusive power of Congress to legislate. Congress already has demonstrated that it is active in these very areas with the enactment of the 1984 DPC-PTR Act, the 1988 Amendments to Section 271(e)(1), and the proposed amendment in 1989. Neither patent law nor the FD&C Act supports Medtronic's newly-asserted alleged exemption.

The Court of Appeals for the Federal Circuit squarely addressed the experimental use exemption in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858, 862-65 (Fed. Cir.), *cert. denied,* 469 U.S. 856 (1984). After reviewing the history of this defense to liability for infringement of a drug patent, the Federal Circuit declined to "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when the inquiry has definite, cognizable and not insubstantial commercial purposes," as does FDA testing to obtain premarket approval. *Id.* at 863. *See also Paper Converting,* 745 F.2d at 16-20 (it is a patent infringement to test a patented product intended solely for post-patent use in a non-regulated industry). Refusing to rewrite the patent laws and indicating that it is the role of Congress

to legislate, the Federal Circuit declined to legislate a new patent infringement exception for drug testing to obtain FDA premarket approval for products. *Bolar,* 733 F.2d at 864-65. The analysis of the *Bolar* court applies equally to medical device patents and is set forth in that reported decision.

Medtronic's newly articulated defense goes hand in hand with its attempt to further delay injunctive relief by requesting a remand to the Court of Appeals.[14] This Court should deny Medtronic's request that the case be remanded to the Court of Appeals for consideration of "other bases for vacating the injunction." Medtronic Br. p. 5, n.4. Medtronic abandoned its only other alleged basis, which Lilly will address briefly.[15]

Although mysteriously not revealed by Medtronic to this Court, presumably because of lack of merit, Medtronic contended that the patent rights for the '757 patent, extended under 35 U.S.C. § 156(b), somehow did not apply to Medtronic's devices during the extended term (October 27, 1988 through October 26, 1990). The plain language of Section 156(b) states that the patent rights are extended for "any use approved for the product" (for product claims)

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[14] Medtronic's request for a remand is yet another facet of Medtronic's overall strategy in this case to delay proceedings and avoid a full injunction against its infringing activities through procedural delay. Already, over six years of the patent life have expired during this litigation (filed in 1983). Medtronic substantially delayed this litigation, *inter alia,* by instituting reexamination proceedings before the Patent Office for the patents now in suit and once owned by Medtronic. Six years of willful infringement and irreparable injury to the patent holder are enough (Pet. App. 37a).

[15] Despite the potentially dispositive nature of Medtronic's Section 156(b) defense to injunctive relief under the '757 patent (which is within its extended term), Medtronic failed to seek reconsideration from the Court of Appeals after its decision remanded the case to the District Court "to decide whether the injunction should be vacated, modified, or stayed." (Pet. App. 7a). Medtronic remained silent while the District Court issued a modified injunction, directly contrary to Medtronic's Section 156(b) defense, and effective during the extended term of the '757 patent.

and "any use claimed by the patent and approved for the product" (for method claims).

In this case, the "use approved" is the treatment of ventricular tachycardia and ventricular fibrillation by electric shock with an automatic implantable defibrillator (TX-600; Pet. App. 23a). Medtronic's use of its devices indisputably is identical to this "use approved" (Pet. App. 24a-25a; JA140). In fact, Medtronic initially used a CPI implantable defibrillator (the approved product) as a backup for its 7215 PCD devices (JA44). This further establishes that Medtronic's devices are used for the "use approved" within Section 156(b). Medtronic's Section 156(b) defense has no merit, and its attempt to revive the defense must be rejected.

CONCLUSION

The decision below is clearly erroneous. Lilly respectfully requests that the judgment of the Court of Appeals be reversed and the case be remanded for further proceedings with instructions to reinstate immediately the District Court's original injunction. *See, e.g.*, 28 U.S.C. § 2106; *Morton v. A Quaker Action Group*, 402 U.S. 926 (1971) (this Court reinstated preliminary injunction); *Lawlor v. National Screen Service Corp.*, 349 U.S. 322, 330 (1955) (judgment of Court of Appeals reversed and case remanded to the District Court for further proceedings). This original injunction, which the Court of Appeals refused to stay during the appeal (Pet. App. 56a), was modified solely on the basis of the Court of Appeals' erroneous interpretation of Section 271(e)(1). Once this Court corrects the Court of Appeals' erroneous interpretation, the *status quo* and fairness require immediate reinstatement of the original injunction. The extended term of the '757 patent expires

on October 26, 1990. Lilly is being continually and irreparably harmed by the lack of a full injunction against Medtronic's infringing activities (Pet. App. 37a).

Respectfully submitted,

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